UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 12, 2021

CLEARPOINT NEURO, INC.

(Exact name of registrant as specified in its charter)

DELAWARE (State or other jurisdiction of incorporation) 001-34822 (Commission File Number) 58-2394628 (I.R.S. Employer Identification Number)

5 Musick Irvine, Ca. 92618 (Address of principal executive offices, zip code)

(949) 900-6833 (Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

D Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.01 par value per share	CLPT	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company ?

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On January 12, 2021, ClearPoint Neuro, Inc. (the "Company") issued a press release announcing its preliminary estimates of revenue for the fourth fiscal quarter and year ended December 31, 2020. A copy of the press release is furnished herewith as Exhibit 99.1.

The information in Item 2.02 of this Form 8-K, as well as Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

Exhibit 99.1 Press Release dated January 12, 2021

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CLEARPOINT NEURO, INC.

By: <u>/s/ Danilo D'Alessandro</u> Danilo D'Alessandro Chief Financial Officer



For Immediate Release

ClearPoint Neuro, Inc. Reports Record Revenue in Preliminary Fourth Quarter 2020 Results

IRVINE, CA, January 12, 2021 ElearPoint Neuro, Inc. (Nasdaq: CLPT) (the "Company"), a global therapy-enabling platform company providing navigation and delivery to the brain, today reported preliminary unaudited revenue results for the quarter and full year ended December 31, 2020.

Preliminary 2020 Results:

- Preliminary unaudited revenue for the fourth quarter of 2020 will be approximately \$3.7 million, an increase of 14% over the same period in 2019. Preliminary revenue for the full-year 2020 will be an estimated \$12.8 million, representing 14% growth from 2019.
- The Company supported 175 cases in the fourth quarter of 2020 against the backdrop of continued postponements of elective procedures due to the COVID-19 pandemic.
- Cash used in operations for the quarter and year ended December 31, 2020, is expected to be approximately \$2.4 million and \$7.9 million, respectively. The full-year amount includes the payment of \$1.0 million in accumulated interest on secured indebtedness that the Company repaid in January 2020.
- The Company had approximately \$20.1 million in cash and cash equivalents at December 31, 2020.

"We were pleased with our revenue performance in the fourth quarter, augmented by capital purchases of ClearPoint installations," commented Joe Burnett, President and Chief Executive Officer of ClearPoint Neuro. "While some hospitals have resumed capital acquisition activities, we, like most of our peers, continue to see the adverse impact of the most recent surge of COVID-19 cases globally, and we expect downward pressure on elective procedures to continue at least through the first half of 2021. I look forward to providing more detail on our full fourth quarter earnings call, the specifics of which we plan to announce next month."

About ClearPoint Neuro

ClearPoint Neuro's mission is to improve and restore quality of life to patients and their families by enabling therapies for the most complex neurological disorders with pinpoint accuracy. Applications of the Company's current product portfolio include deep-brain stimulation, laser ablation, biopsy, neuro-aspiration, and delivery of drugs, biologics, and gene therapy to the brain. The ClearPoint® Neuro Navigation System has FDA clearance, is CE-marked, and is installed in 60 active clinical sites in the United States. The Company's SmartFlow® cannula is being used in partnership or evaluation with 25 individual biologics and drug delivery companies in various stages from preclinical research to late-stage regulatory trials. To date, more than 4,000 cases have been performed and supported by the Company's field-based clinical specialist team which offers support and services for our partners. For more information, please visit www.clearpointneuro.com.

Forward-Looking Statements

Statements herein concerning the Company's plans, growth and strategies may include forward-looking statements within the context of the federal securities laws. Statements regarding the Company's future events, developments and future performance, as well as management's expectations, beliefs, plans, estimates or projections relating to the future, are forward-looking statements within the meaning of these laws. Uncertainties and risks may cause the Company's actual results to differ materially from those expressed in or implied by forward-looking statements. Particular uncertainties and risks include those relating to: the impact of COVID-19 and the measures adopted to contain its spread; future revenues from sales of the Company's ClearPoint Neuro Navigation System products; the Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint Neuro Navigation System products; and estimates regarding the sufficiency of the Company's cash resources. More detailed information on these and additional factors that could affect the Company's actual results are described in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, and the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2020, both of which have been filed with the Securities and Exchange Commission, and the Company's Annual Report on Form 10-K for the year ended December 31, 2019.

Contact:

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